

Five specialty pharmaceutical trends to watch

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Approvals of specialty pharmaceuticals have far outpaced traditional drugs, and that trend will continue. But that's not the only specialty medication trend that healthcare executives should have on their radar.



Tharaldson During her October 4 session, "Specialty Pharmaceuticals in Development," at the Academy of Managed Care Pharmacy (AMCP) Nexus 2016, in National Harbor, Maryland, Aimee Tharaldson, PharmD, senior clinical consultant, emerging therapeutics, at Express Scripts, explained how the growth in specialty medications is affecting managed care pharmacy.

Here are five noteworthy specialty medication trends Tharaldson identified during her presentation:

1. Specialty approvals will continue to outpace traditional medications. For the past six years the FDA has approved more specialty than traditional medications, said Tharaldson. Last year, 56 new drugs were approved, 33 of which were specialty medications.

2. Specialty medications will face more competition. Competition in specialty medications is growing (including among generic specialty medications), as more medications are approved, and as more medications impact orphan conditions and cancer, said Tharaldson.

She also noted that biosimilars could increase competition, once they overcome "litigation hurdles."

3. Biosimilars are gaining traction. The FDA has approved four biosimilars and many more are in the pipeline, said Tharaldson.

The approved biosimilars are:

- **Sandoz's Zarxio (filgrastim-sndz), approved in March 2015 and launched in September 2015.** This is a noninterchangeable biosimilar to Amgen's Neupogen (filgrastim). It is approved for neutropenia, and has a wholesale list price 15% less than Neupogen, said Tharaldson.

- **Inflectra (infliximab-dyyb), from Pfizer, approved in April 2016.** This is a noninterchangeable biosimilar to Janssen's Remicade (infliximab). It is approved for rheumatoid arthritis, ulcerative colitis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and Crohn's disease (adult and pediatric). Launch was expected this month, but litigation could delay this, said Tharaldson.

- **Sandoz's Erelzi (etanercept-szszs), approved in August 2016.** This is a noninterchangeable biosimilar to Amgen's Enbrel (etanercept). It is approved for rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, and juvenile idiopathic arthritis. Launch is possible in February 2017, but it's likely to be delayed, said Tharaldson.

- **Amgen's Amjevita (adalimumab-atto), approved in September 2016.** This is a noninterchangeable biosimilar to AbbVie's Humira (adalimumab). It is approved for rheumatoid arthritis, psoriasis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis and juvenile idiopathic arthritis. It could be launched in March 2017, but will likely be delayed, said Tharaldson.

There are also several biosimilars currently pending approval, said Tharaldson. They are:

- Filgrastim (Grastofil, Apotex)
- Pegfilgrastim (Apotex)
- SB2 infliximab (Merck/Samsung Bioepis)
- CHS€1701, a pegfilgrastim (Coherus Biosciences)
- Epoetin alfa (Retacrit, Pfizer)

4. Cancer drug development is a key focus area. About 1.7 million cases of cancer are diagnosed each year in the U.S. Still, the cancer death rate has fallen 23% since the early 1990s, due to a drop in smoking, better and earlier diagnosis, and new medications and treatments, said Tharaldson.

The "development of cancer medications is very extensive," she said, noting that in the last year, 15 new cancer medications were approved. Though not as many are likely to be approved this year, Tharaldson said the trend toward more cancer medications will continue.

5. Orphan drug development will continue to expand. There are approximately 7,000 orphan diseases affecting 30 million patients in the U.S., said Tharaldson, noting that these medications are extremely expensive.

"About 40% of the specialty pipeline is focused on orphan medications," she said. When orphan medications and cancer medications are combined, they make up about two-thirds of the specialty pipeline.